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APPLICATION NUMBER: *60/509,528*
FILING DATE: *October 09, 2003*
RELATED PCT APPLICATION NUMBER: *PCT/US04/33385*

Certified by

Jon W Dudas

Acting Under Secretary of Commerce
for Intellectual Property
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PTO/SB/16 (08-03)
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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No.

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
George B. Edward J.	Cipolletti Cheal	Duxbury, MA Duxbury, MA

Additional inventors are being named on the 0 *separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

Modular tapered hip prosthesis

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

☐ Customer Number:

OR

☑ Firm or Individual Name	Apex Surgical, LLC				
Address	12 Harding Street				
Address	Suite 202				
City	Lakeville	State	MA	Zip	02347
Country	USA	Telephone	208-947-6500	Fax	208-248-8227

ENCLOSED APPLICATION PARTS *(check all that apply)*

☑ Specification *Number of Pages* 11 ☐ CD(s), Number

☑ Drawing(s) *Number of Sheets* 3 ☐ Other (specify)

☐ Application Date Sheet. See 37 CFR 1.76

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☑ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check or money order is enclosed to cover the filing fees.

☐ The Director is herby authorized to charge filing fees or credit any overpayment to Deposit Account Number:

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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☑ No.

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Respectfully submitted,

SIGNATURE

Date 10-7-03

REGISTRATION NO. *(if appropriate)*

TYPED or PRINTED NAME George B. Cipolletti

Docket Number:

TELEPHONE 508-947-6500 x10

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This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Mail Stop Provisional Application, Commissioner f r Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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FEE TRANSMITTAL for FY 2003

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☑ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 80.00

Complete if Known	
Application Number	
Filing Date	
First Named Inventor	George B. Cipolletti
Examiner Name	
Art Unit	
Attorney Docket No.	

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FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	750	2001	375	Utility filing fee	
1002	330	2002	165	Design filing fee	
1003	520	2003	260	Plant filing fee	
1004	750	2004	375	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	80.00

SUBTOTAL (1) ($) 80.00

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

	Extra Claims		Fee from below	Fee Paid
Total Claims		-20** =		X =
Independent Claims		- 3** =		X =
Multiple Dependent				=

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	84	2201	42	Independent claims in excess of 3
1203	280	2203	140	Multiple dependent claim, if not paid
1204	84	2204	42	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	410	2252	205	Extension for reply within second month	
1253	930	2253	465	Extension for reply within third month	
1254	1,450	2254	725	Extension for reply within fourth month	
1255	1,970	2255	985	Extension for reply within fifth month	
1401	320	2401	160	Notice of Appeal	
1402	320	2402	160	Filing a brief in support of an appeal	
1403	280	2403	140	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,300	2453	650	Petition to revive - unintentional	
1501	1,300	2501	650	Utility issue fee (or reissue)	
1502	470	2502	235	Design issue fee	
1503	630	2503	315	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	750	2809	375	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	750	2810	375	For each additional invention to be examined (37 CFR 1.129(b))	
1801	750	2801	375	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

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SUBMITTED BY			(Complete if applicable)	
Name (Print/Type)	George B. Cipolletti	Registration No. (Attorney/Agent)	Telephone	508-947-6500
Signature			Date	10-7-03

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Provisional Application for : Modular Tapered Hip Prosthesis

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Provisional Applicati n

Field of the Invention

The present invention relates generally to an implantable article that is particularly suitable for use as a component of an artificial joint prosthesis and more particularly to a component having a stem or shaft for insertion within a medullary canal of a bone, such as the femoral component of a hip prosthesis.

Background of the Invention

Artificial hip joint prostheses are widely used today, restoring mobility to patients affected by a variety of conditions, particularly arthritis. The satisfactory performance of these devices can be affected not only by the design of the component itself, but also by the final placement and geometry of the implanted component, and the long-term fixation of the device. Improper placement or positioning of the device or an improper fit to the patient's anatomy can adversely affect the goal of satisfactorily restoring the clinical bio-mechanics and function of the joint.

The primary role of the artificial hip prosthesis is to restore the diseased and/or damaged joint to normal function. This function results in significant forces such as axial, bending, and rotational forces, being imparted to the device. The component must endure these forces while remaining adequately fixed within the medullary canal, because adequate fixation of the component is necessary to ensure proper functioning and a long useful life of the artificial hip component. Early designs of artificial hip components relied primarily on cemented fixation. These cements, such as polymethylmethacrylate, were used to anchor the component within the medullary canal by acting as a grouting agent between the component and the endosteal (inner) surface of the bone. While this method of fixation by cement provides immediate fixation and

resistance to the forces encountered, and allows the surgeon to effectively position the device before the cement sets, it is not without problems. Over time the mechanical properties and the adhesive properties of the bone cement degrade; eventually the forces overcome the cement and cause the components to become loose due to a failure at the cement/bone or cement/stem interface. Alternative approaches to address the issue of cement failure include both biological ingrowth and press-fit stems, separately and in combination.

Stems designed for biological ingrowth typically rely on the bone itself to grow into a specially prepared surface of the component, resulting in firmly anchoring the device within the medullary canal. A shortfall of this approach is that it does not result in immediate fixation of the component (which is distinguished from components which utilize cement fixation), because it takes time for the bone to grow into the specially prepared surface. Press-fit stems may or may not have specially prepared surfaces and typically rely on an interference fit of some degree of the component within the medullary canal of the bone to achieve stable fixation. One particular type of press-fit stem is tapered in one or more planes such that the degree of press-fit of the stem into the medullary canal increases as the stem is more deeply seated into canal. While a tapered stem design has the advantage of reliably producing a stable press-fit condition in the bone, provided the stem is properly sized for the particular bone, the final position of the stem will depend on a number of variables, including bone geometry, bone quality, stem geometry, and surgical technique.

The positioning of the device, including the location of the head center relative to the medullary stem portion, affects the biomechanics of the joint. More optimal positioning results in a more efficient joint, and thus lower forces on the device. It is therefore desirable to provide a component that de-couples the engagement or spacing portion of the stem with the final

positioning of the head center, to allow for both optimal positioning and secure engagement to be achieved, independent of each other.

The hip head center of rotation is determined by the head position because typical hip heads are spherical. In most devices the head position is determined by the stem position because the two are connected through an integral neck. Many devices in existence use modular hip heads to increase or decrease neck length, which alters both head height and head offset proportionately and simultaneously. The neck portion of the device that is attached to the stem receives the modular heads. This results in the head position being integrally linked and thus aligned with and determined by, the stem portion. Multiple positions of the heads are accomplished by using hip heads with various bore dimensions and extended or reduced offsets or skirts which limit the positioning of the head to the angled neck axis. In many instances this may not be appropriate as one may only wish to increase offset while maintaining head height (or vice versa), which can not be accomplished with the modular head type devices previously described. In addition, one could not address anteversion of the neck in such a device as described. The amount of anteversion is determined by the angular difference between the stem-axis/neck-axis plane to that of the coronal plane. Since the head position is directly linked to the stem position, anteversion can only be achieved by sacrificing stem position by rotating the stem. Thus it would be beneficial to be able to achieve variable positioning of the hip center of rotation independent of stem position as well as independent of both head offset and head height. The ability to de-couple hip head center of rotation from stem positioning would be an additional benefit because it would allow for more freedom in stem placement independent of neck axis placement to achieve the desired anteversion. Addressing these items is important in both cemented and cementless applications.

Some devices incorporate modular components, such as modular stems with modular sleeves, or modular proximal and distal portions of the stem, to provide some degree of

adjustability for the final stem geometry. This adjustability may or may not include lateral offset, leg length, and/or anteversion, depending on the specifics of the design and on the available components. Such devices have used two basic means of connection, tapers and threads, used alone or in combination. Taper connections have the disadvantage that the final axial position of the two components, relative to each other, is dependent on the precise geometry of the tapers; deviations in geometry within the tolerances allowed for manufacturing results in deviations in the final axial position of the modular component with the tapered connection. The strength of the coupling between the components with the tapered connection is also in part dependent on the level of force used to assemble the components. Similarly, threaded connections have the disadvantage that the strength of connection is in part dependent on the magnitude of torsion applied to the threaded coupling mechanism during assembly. Insufficient impaction force for tapered connections, and/or insufficient torsion for threaded connections, applied during assembly can leave the assembled component at risk of disassembly during the functional lifetime of the device. Unintended disassembly of implanted components is a serious complication that generally requires medical intervention ranging in severity from closed manipulation to surgical revision. This can be a significant risk for tapered and/or threaded coupling means especially considering that the assembly is accomplished in the operating room, rather than under more controlled conditions such as in a factory, in order to take full advantage of the modularity. Thus a design that provides a coupling means for the modular components that has a more reproducible final geometry and reproducible strength of connection, that is less dependent on the surgeon, operating room staff, or other persons acting outside the place of manufacture, would be of significant benefit.

Summary of the Invention

Accordingly, it is an object of the invention to provide a component designed to allow for neck geometry and rotational neck positioning independent of the engagement/positioning of the stem portion of the component after full insertion of the stem portion is achieved. In this way one can accommodate variable head positioning independently and more extensively by utilizing different and distinct modular proximal body portions that result in differing ratios of head-offset to head-height when combined with selected modular hip heads. One can also accommodate a degree of unpredictability in placement and seating of the stem by selection of the proximal body portion after insertion of the stem portion into the medullary canal. Separate proximal portions have the additional benefit of being able to address anteversion of the head position independent of stem placement. The components that comprise these devices are designed such that assembly of the components can be accomplished either before implantation, such as on the back table during surgery, or, alternatively the assembly can be accomplished in a successive fashion, assembling each portion independently during implantation to maximize the benefits of independent positioning of the individual sub-components of the device within the bone.

The cylindrical press-fit coupling means between the proximal body portion and the stem portion provides a reproducible strength and geometry of assembly between the two portions; this coupling means only requires axial translation of the proximal body portion into the stem portion, where full assembly is defined by seating of the proximal body portion to the stem portion, which could not be achieved with the use of a tapered coupling means. Provided the two portions are fully assembled, the resulting strength of assembly and the axial position of the proximal body portion relative to the stem portion are dependent on the design and

manufacturing tolerances, and are not dependent on the magnitude of force applied during assembly, unlike tapered and/or threaded coupling means.

These and other objects are achieved in which the stem and proximal body portions are de-coupled resulting in two distinct pieces. The modular proximal body portion may be combined with the modular stem portion to allow additional rotational alignment and positioning of the proximal body portion independent from and relative to the stem. This achieves additional variable positioning independent of that achieved after insertion of the stem portion. The modular proximal body portion can be locked to the stem portion in one of several positions to achieve the desired amount of rotational alignment. By varying proximal body portion configurations a variety of clinical needs and situations can be addressed such as calcar replacement type devices or satisfying the need of extremely offset necks without requiring a whole new stem system. Many more clinical situations can be addressed by simply using the appropriate proximal body portion configuration designed for that purpose.

The stem portion utilizes a tapered external geometry for interfacing with the recipient bone such that a press-fit of the stem is achieved as the stem is inserted into the prepared medullary canal. Prior to stem insertion, the canal is prepared using one or more reamers, broaches, rasps, or similar instruments to create the appropriate cavity in the recipient bone. After preparation of the bone, the stem is forcibly inserted into the prepared cavity until the proper rotational position and sufficient insertion depth and press-fit stabilization are achieved. Through the availability of a selection of proximal body portions with various geometries and rotational positions, various stem positions after insertion can be accommodated while still achieving the proper final geometry of the implant assembly.

Additional positioning options exist with the addition of modular heads that are assembled to one of the several proximal-body portions envisioned to achieve independent head

offset and head height options. Due to the extent of options available, and the desire for a system approach in addressing a multitude of clinical situations with limited components, connection means between the components is simplified and common amongst the components resulting in a reliable, more cost effective, and user friendly means to secure the components either prior to, immediately prior to, or during implantation.

Brief Description of the Drawings

FIG. 1 is an exploded view of the prosthetic device of the present invention.

FIG. 2 is a section view of the prosthetic device of the present invention.

FIG. 3 is a view of the proximal body portion of the prosthetic device of the present invention.

Detailed Description of the Invention

The present invention is particularly related to the femoral component of an artificial hip prosthesis for both cemented and cementless applications; however the invention is also applicable to other implantable prostheses such as knees, elbows and shoulders, all of which may include a stemmed portion for insertion into a bone cavity. The present invention is particularly advantageous in allowing optimal placement and secure attachment for use in an artificial hip and as such this description will reference a hip prosthesis.

As shown in FIG. 1 there is an elongated stem portion (1) of the device that is the portion that is inserted into the medullary canal of the bone. The stem portion (1) is independent from the proximal body portion (2), the two portions being assembled and joined by the locking means shown in FIG. 2. Modular hip heads (3) can be attached to the neck (16) of the proximal body portion to complete the device. The assembly of the device is not limited temporally, in that assembly can occur before surgery, immediately prior to implantation, or during implantation. The attachment means described below allows for ease of assembly with limited access.

The distal portion (9) of the stem is generally round, elliptical, or rectangular in cross-section, or some combination of these shapes. The stem is tapered such that the cross-sectional area of the stem is generally increasing from the distal portion (9) to the mid shaft portion (10),

and further in the mid shaft portion (10) to the proximal portion (11), continuing to the proximal end (12). The taper may be in the medial-lateral dimension only, or may be in both the medial-lateral dimension and the anterior-posterior dimension. The distal (9) mid shaft (10) and/or proximal portions (11) may include grooves, slots, or longitudinal ridges with intervening flutes to aid in positioning of the stem and to provide increased rotational stability of the stem in the bone. These grooves, slots, ridges and/or flutes may extend to or near the distal end of stem or may be limited to the mid shaft portion of the stem. The mid shaft portion (10) blends into the relatively larger proximal portion (11) of the stem which tends to follow the bone contour of the canal being larger on the medial side of the device. Located on the proximal end (12) of the stem is a cylindrical bore (14) which may aligned with the longitudinal stem axis or may be oriented at an angle to the longitudinal stem axis. The cylindrical bore (14) may include a blind hole at the base (8). This hole (8) may include threads or other feature for engaging a screw, bolt, rod, or similar, which may be removably engaged to the stem portion (1). Such rod, or similar, may be used as part of an assembly device, to apply an assembly force to the stem while such device applies an opposite force to the proximal body portion (2), to forcibly assemble the proximal body portion into the stem portion. The hole (8) may also serve as a means of removing the stem from the bone in which the stem is implanted using a suitable instrument that removably engages the stem. In one embodiment of the present invention, the proximal surface of the stem (12) may include a key, tab, or pin (18) for rotational alignment of the proximal body portion. This alignment feature (18) may also contribute to the torsional strength of the modular junction.

Stem diameters for this hip prosthesis range in size from 8 to 20 mm and would be suitable for most of the population. Patients requiring sizes smaller or larger, although uncommon, are accommodated through custom or patient specific devices.

The proximal body portion (2) is independent of the stem portion (1) and assembled and joined to the stem portion by the user (surgeon). This modular feature is what allows the surgeon additional flexibility in final stem placement. By de-coupling stem placement from proximal body placement, substantially more flexibility is allowed and the ability to address anteversion becomes available. The number of rotational positions of the proximal body portion (2) can be quite large, however as a matter of manufacturing practicality, the positions can be limited to several discreet positions and still address the positioning need by the surgeon during implantation. In addition, optimal positioning (including lateral offset and leg length) may be achieved by choosing the appropriate proximal body portion to use with the chosen stem portion. For instance, for a given

stem, the combination of 9 unique proximal bodies coupled with 4 modular heads with varying offsets, gives the surgeon the choice of 36 lateral offset/leg length positions. In addition, each of these 36 positions can be further adjusted by rotation of the proximal body portion independent of the stem portion prior to final seating of the proximal body portion, resulting in the desired combination of anteversion, lateral offset, and leg length. Primary positioning is obtained by indexing the keyed portion (18) of the stem (1) to that of the receiving slot or holes (17) of the proximal body (2). While a minimum of two to as large as twelve discreet positions are obtainable, it is preferred to have three (17) to six discreet positions of the proximal body portion (2).

Final locking of the proximal body portion (2) to the stem portion (1) is obtained by the male spigot (15) of the proximal body portion (2) locking within the corresponding bore (14) of the stem portion (1). This locking is achieved by one or more zones of diametrical interference between the spigot and bore. In the zones of diametrical interference on the spigot (15) and the corresponding zones of diametrical interference on the bore (14), the spigot and bore are cylindrical. To obtain the interference fit between the spigot and bore at these zones (4 and 5), the outside diameter of the spigot exceeds the inside diameter of the bore, which defines the diametrical interference. The diametrical interference between the spigot and the bore is critical to proper functioning of the device, and may be in the range of 0.0005" to 0.0035". The preferred embodiment utilizes a nominal diametrical interference of 0.0020" at the proximal end of the spigot (4) and bore and a nominal diametrical interference of 0.0010" at the distal end of the spigot and bore (5). The length of the zone of diametrical interference may be limited to approximately 0.020" to 0.080" to provide adequate rotational resistance of the proximal body portion within the stem portion, while maintaining reasonable assembly forces by controlling the amount of interference, the length of the zone and the axial location of the zone(s). In the preferred embodiment, both the spigot (15) and bore (14) incorporate gradual tapers and/or rounds at the surfaces leading into the zones of diametrical interference so as to avoid plowing of one or more surfaces during assembly, and thus ease assembly of the proximal body portion to the stem portion. The length of the spigot (15) is not critical, it only requires a length adequate to ensure a suitable locking surface and adequate axial engagement. It has been determined that a length of approximately 0.8" is satisfactory for the femoral component of a hip replacement.

The modular proximal body portion (2) also allows one to utilize different neck configurations (16) with the same stem portion (1) allowing for multiple options for each and every stem. Variations of proximal body portions (2) can include, both different angled necks and

neck lengths alone or in combination with each other to achieve varying head positioning. When modular heads (3) are attached to these varying proximal body portions (2) the design options multiply significantly with very little increase in number of individual sub-components such as modular heads and proximal body portions. The neck (16) of the proximal body portion (2) is attached to the base from which the neck (16) projects outward usually at an angle of 40 to 50 degrees from the long axis of the stem, preferably 45 degrees. The cross section geometry of the neck is generally round. Flat cutouts on the neck (16) may be incorporated to maximize the range of motion before impingement of the neck occurs on the surrounding bone of the acetabulum. One end of the neck (16) is blended into the base of the proximal body while the opposite end forms a conical tapered plug (6). The conical tapered plug (6) receives the modular hip heads (3) that have a corresponding tapered bore. The modular hip heads (3) are sized such that they fit into a corresponding acetabular cup component. Metal or ceramic hip heads commonly used in implantable hip prostheses can be used with this component as long as the hip heads (3) have a suitable corresponding tapered bore that mates with the conical tapered plug (6) at the end of the neck (16).

The proximal body portion (2) may include a bore hole (7) through the spigot (15). This bore hole (7) may include threads or other means for removable engagement of a bolt, rod, or plug, separately and for various purposes. The bolt or rod could provide a means of removing the neck from the stem, or removing the assembled construct from the bone. The plug could be used to close the hole and keep the internal surfaces clean. The bore hole (7) could also be used to enable a rod to pass through the proximal body portion (2), said rod removably engaging the stem portion (1) at the hole (8), as part of a device to forcibly assemble the proximal body portion into the stem portion.

The stem (1), proximal body (2), and head portions (3) of this device can be fabricated from any suitable high strength biocompatible material. Suitable materials include any of the titanium alloys, cobalt alloys, or stainless steel alloys. Preferred examples include Ti-6Al-4V for the stem and proximal body portions, and Co-Cr alloys for the head portion.

FIG. 1

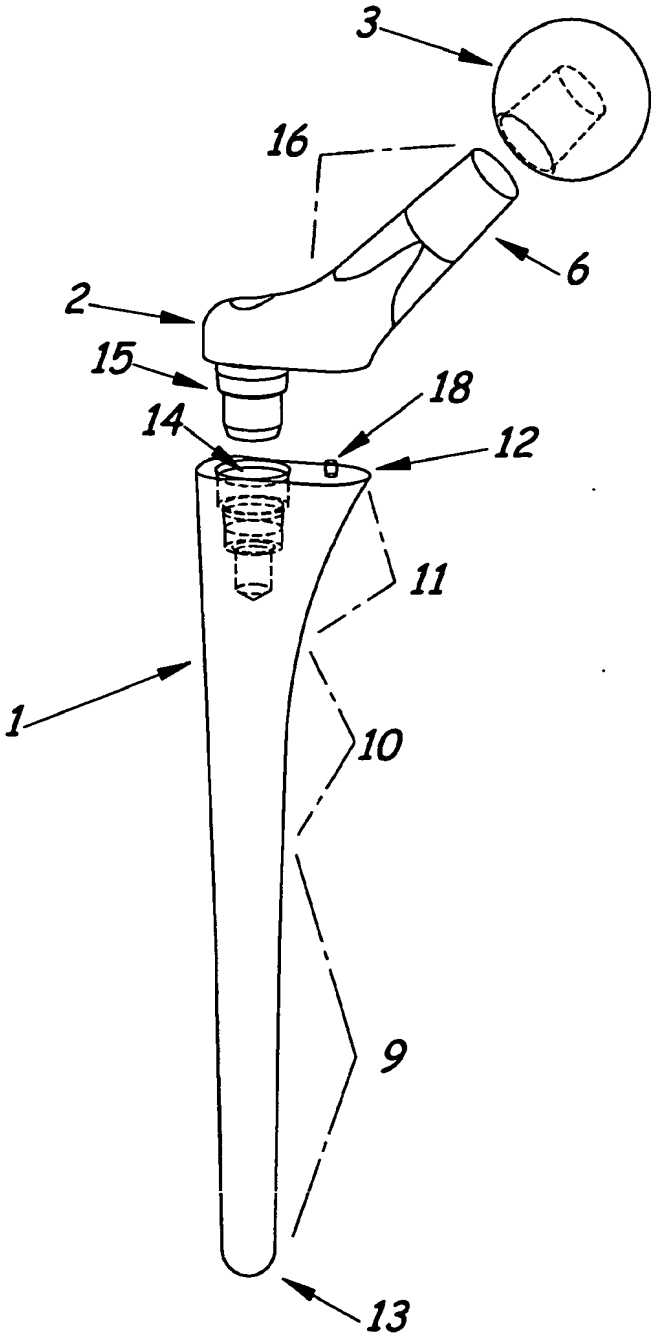


FIG. 2

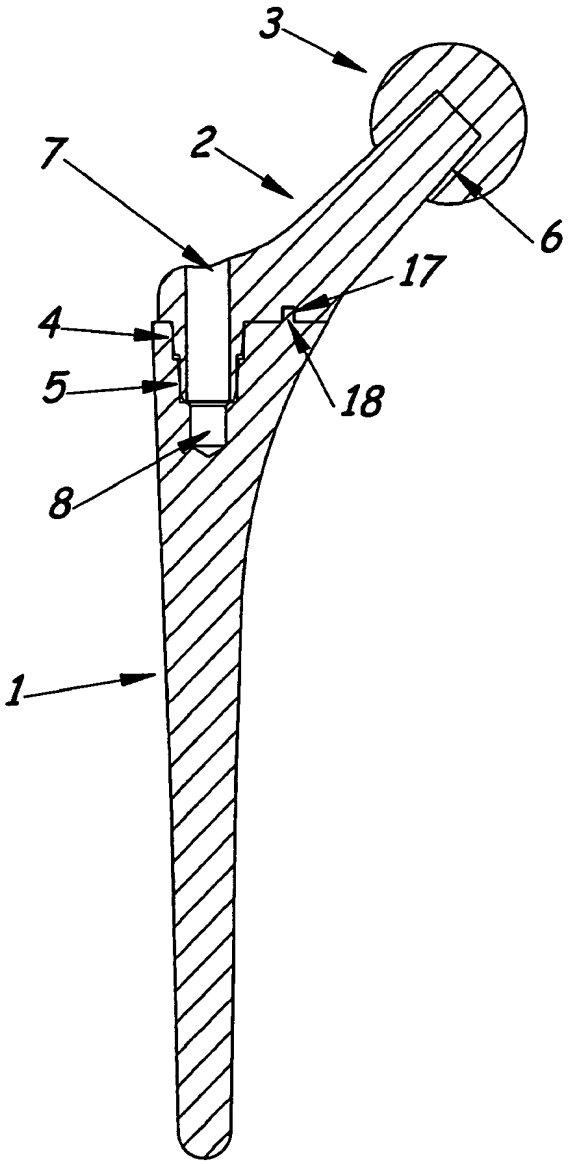
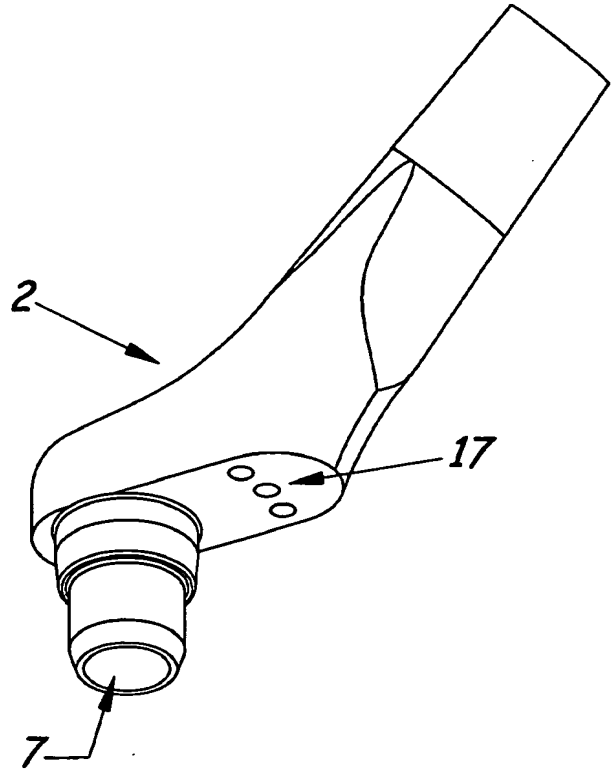


FIG. 3



Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/US04/033385

International filing date: 08 October 2004 (08.10.2004)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/509,528
Filing date: 09 October 2003 (09.10.2003)

Date of receipt at the International Bureau: 12 November 2004 (12.11.2004)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)

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